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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Robert A. Ashley Examiner: Unassigned
Serial No.: 10/757,656 Group Art Unit: 1617
Confirmation No: 3939 Docket: 512-53 DIV
Filed: January 14, 2004 Dated: May 24, 2006
For: METHODS OF TREATING
ACNE

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

I hereby certify this correspondence is being deposited
with the United States Postal Service as first class mail,
postpaid in an envelope addressed to Commissioner for
Patents, PO Box 1450, Alexandria, VA 22313-1450

on May 24, 2006 Signature Carla H. Bryan

**SECOND SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT**

Sir:

In order to fulfill the requirements of candor and good faith set forth in 37 C.F.R. §1.56, Applicant submits herewith the following Information Disclosure Statement in accordance with the provisions of 37 C.F.R. 1.97 and §1.98. The Information Disclosure Statement is being timely submitted under 37 C.F.R. 1.97(b)(4), i.e., before the mailing of a first office action.

UNITED STATES PATENT

| <u>PATENTEE</u> | <u>PATENT NO.</u> | <u>ISSUE DATE</u> |
|------------------------|--------------------------|--------------------------|
| Arbiser | 6,673,843 | January 6, 2004 |

UNITED STATES PATENT PUBLICATION

| <u>APPLICANT</u> | <u>PUBLICATION NO.</u> | <u>PUBLICATION DATE</u> |
|-------------------------|-------------------------------|--------------------------------|
| Milstein | US 2003/0082120 A1 | May 1, 2003 |

NON-PATENT PUBLICATIONS

1. Akamatsu et al. "Effects of subminimal inhibitory concentrations of minocycline on neutrophil chemotactic factor production in comedonal bacteria, neutrophil phagocytosis and oxygen metabolism." *Arch Dermatol Res* 283:524-528 (1991).
2. Bikowski et al. "Treatment of Rosacea with Doxycycline Monohydrate" *Cutis* 66:149-152 (Aug. 2000).
3. Golub et al. "Tetracyclines Inhibit Connective Tissue Breakdown: New therapeutic Implications for an Old Family of Drugs" *Critical Reviews in Oral Biology and Medicine*, 2(2):297-322 (1991).
4. Illig, L. (a) Original German article: "Positive Nebenwirkungen antibiotischer bzw. antimikrobieller Substanzen in der Therapie" (b) English translation: "Positive side effects of antibiotic and antimicrobial substances in therapy" *Infection*, 7 (Suppl. 6) 584-588 (1979).
5. Knight et al. "A follow-up of tetracycline-treated rosacea" *British Journal of Dermatology* 93:577-580 (1975).
6. Marks et al. "Comparative Effectiveness of Tetracycline and Ampicillin in Rosacea" *The Lancet* 1049-1052 (November 13, 1971).
7. Millar et al. "A general practice study investigating the effect of minocycline (Minocin) 50 mg bd for 12 weeks in the treatment of acne vulgaris" *The British Journal of Clinical Practice* 41(8):882-886 (August 1987).
8. Plewig et al. Acne: Morphogenesis and Treatment, Springer-Verlag 261, 297-301 (1975).

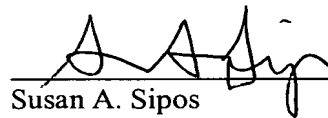
Applicant(s): Robert A. Ashley
Serial No: 11/757,656
Filed: January 14, 2004
Our Docket: 512-53 DIV
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9. Webster et al. "Suppression of Polymorphonuclear Leukocyte Chemotactic Factor Production in *Propionibacterium acnes* by Subminimal Inhibitory Concentrations of Tetracycline, Ampicillin, Minocycline, and Erythromycin" *Antimicrobial Agents and Chemotherapy* 21(5):770-772 (1982).

Copies of the references set forth above were provided in the parent application USSN 10/117,709, and a separate listing of the same has been set forth on the attached Form PTO-1449. The examiner is respectfully requested to consider each of these references in its entirety, and to indicate that she or he has done so by initialing the Form PTO 1449.

Applicant is not aware of any other references to be identified at this time. If the examiner has any questions or comments relating to the present application, she or he is respectfully invited to contact applicant's attorney at the telephone number set forth below.

Respectfully submitted,



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| FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Rev. 2-32) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) | ATTY. DOCKET NO. 512-53 DIV | SERIAL NO. 10/757,656 |
| | APPLICANT Robert A. Ashley | CONFIRMATION NO. 3939 |
| | FILING DATE January 14, 2004 | GROUP 1617 |

U.S. PATENT

| EXAMINER INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB CLASS | FILING DATE IF APPROPRIATE |
|---------------------|--------------------|--------|----------|-------|--------------|-------------------------------|
| | 6,673,843 | 1/6/04 | Arbiser. | 514 | 679 | June 30, 1999 |

U.S. PATENT PUBLICATIONS

| EXAMINER INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB CLASS | FILING DATE IF APPROPRIATE |
|---------------------|--------------------|--------|-----------|-------|--------------|-------------------------------|
| | 20030082120 | 5/1/03 | Milstein. | 424 | 59 | October 24, 2002 |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | |
|--|---|---|
| | 1 | Akamatsu, et al. "Effects of subminimal inhibitory concentrations of minocycline on neutrophil chemotactic factor production in comedonal bacteria, neutrophil phagocytosis and oxygen metabolism." <i>Arch Dermatol Res</i> 283:524-528 (1991) |
| | 2 | Bikowski, et al. "Treatment of rosacea with doxycycline monohydrate" <i>Cutis</i> , 66:149-152 (Aug 2000) |
| | 3 | Golub, et al. "Tetracyclines inhibit connective tissue breakdown: New therapeutic implications for an old family of drugs" <i>Critical Reviews in Oral Biology and Medicine</i> , 2(2):297-322 (1991) |
| | 4 | Illig "Positive side effects of antibiotic and antimicrobial substances in therapy" <i>Infection</i> 7 (Suppl. 6): S 584-588 (1979) (English translation. Original document in German.) |
| | 5 | Knight, et al. "A follow-up of tetracycline-treated rosacea" <i>British Journal of Dermatology</i> 93:577-580 (1975) |
| | 6 | Marks, et al. "Comparative effectiveness of tetracycline and ampicillin in rosacea" <i>The Lancet</i> , 1049-1052 (November 13, 1971) |

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DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.

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| | APPLICANT Robert A. Ashley | CONFIRMATION NO. 3939 |
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| | | 7 | Millar, et al. "A general practice study investigating the effect of minocycline (Minocin) 50 mg bd for 12 weeks in the treatment of acne vulgaris" <i>The British Journal of Clinical Practice</i> 41(8):882-886 (August 1987) |
| | | 8 | Plewig, et al. <u>Acne: Morphogenesis and Treatment</u> , Springer-Verlag 297-301 (1975) |
| | | 9 | Webster, et al. "Suppression of Polymorphonuclear Leukocyte Chemotactic Factor Production in <i>Propionibacterium acnes</i> by Subminimal Inhibitory Concentrations of Tetracycline, Ampicillin, Minocycline, and Erythromycin" <i>Antimicrobial Agents and Chemotherapy</i> 21(5):770-772 (1982) |

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